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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,490	03/29/2004	Robert G. Johnson JR.	010083.02	8300
7590 06/29/2007				
Gary W. Ashley Kosan Biosciences, Inc. 3832 Bay Center Place Hayward, CA 94545				
			EXAMINER HAGOPIAN, CASEY SHEA	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 06/29/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/814,490

Applicant(s)

JOHNSON, ROBERT G.

Examiner

Casey Hagopian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/2/05 10/17/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicant's Oath filed 8/19/2004 and Information Disclosure Statements filed 5/2/2005 and 10/17/2005.

Claim Objections

Claim 6 is objected to because of the following informalities: the claim is missing a "." at the end of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Ashley et al. (US 2003/0045711 A1).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

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the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Ashley teaches coated stents to treat restenosis, the coating including a therapeutic agent comprising a derivative of epothilone D (paragraphs 0004 and 0250-0251). Thus, the disclosures of Ashley anticipate the instant claim set.

Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Santi et al. (US 2003/0114450 A1).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Santi teaches coated stents to treat restenosis, the coating including one or more compounds including epothilones and geldanamycins, specifically 17-allylamino-17-desmethoxygeldanamycin (17-AAG) and 17-[2-(dimethylamino)ethylamino]-17-desmethoxygeldanamycin (17-DMAG) (paragraphs 0105, 0122-0123, and 0132-0145). Santi also teaches the particular drug combination of a benzoquinone ansamycin (e.g. 17-AGG or 17-DMAG) and a stabilizing microtubule (e.g. epothilone D) (paragraph 0105 and 0109). Thus, the disclosures of Santi render the instant claims anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ashley et al. (US 2003/0045711 A1) in view of Carlyle et al. (US 2002/0127263 A1).

Ashley teaches the elements discussed in the paragraphs above.

Ashley is silent to the compounds, rapamycin and geldanamycin. Ashley is also silent to a polymer.

Carlyle teaches compositions and methods thereof comprising at least one thiazolidinedione in combination with at least one additional therapeutic agent for the treatment of restenosis (abstract, paragraph 0028, and claims 22 and 24-25). In particular, Carlyle teaches coated stent comprising said compositions. Also, Carlyle teaches rapamycin as well as geldanamycin (paragraph 0028). Rapamycin is well known in the art to be effective alone or in conjunction with other therapeutic agents against restenosis. Carlyle further teaches polymers including polycaprolactone, polyethylene glycol, and poly-L-lactic acid (paragraph 0011).

One of ordinary skill in the art would have been motivated to either replace or combine compounds taught in the relevant art as being able to treat the same disorder because they are appreciated as equivalents among the art. Absent of unexpected results, a practitioner would have reasonably expected a medical device comprising a composition comprising one or medicaments capable of treating restenosis. Thus, in Ashley, it would have been obvious to one skilled in the art to include rapamycin and/or geldanamycin as suggested by Carlyle into the coated medical device in order to treat restenosis.

One of ordinary skill in the art would have been motivated to including a polymer into the coating of a medical device because the polymer would control the elution rate of the compound(s). A practitioner would have reasonably expected a medical device coating with a composition containing a polymer and one or more therapeutics capable

of various release profiles depending on the polymeric formulation. Thus, in Ashley, it would have been obvious to one skilled in the art to include a polymer as suggested by Carlyle in order to control the release of said compounds.

Conclusion

All claims have been rejected; no claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Casey Hagopian

Casey Hagopian
Examiner
Art Unit 1615

Carlos A. Azpuru

CARLOS A. AZPURU
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GROUP 1500